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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,848	01/14/1999	TERUAKI SEKINE	1208/P502PCT	8123

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
05/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/214,848	Applicant(s) SEKINE, TERUAKI	
	Examiner Frank I. Choi	Art Unit 1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *16 November 2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *13,14,19-27,31,32,34 and 36-38*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

JOHANN RICHTER
SUPERVISORY PATENT EXAMINER
GROUP 1200

Continuation of 11. does NOT place the application in condition for allowance because: The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Action(6/16/2006) and the further reasons below. Although, the Applicant is correct in indicating that activating with the antibody is preferred in Ochoa '353, Ochoa '353 clearly indicates that activating invitro with both IL-2 and anti-CD3 antibody is within the scope of the invention disclosed in said reference (Column 8, lines 60-65). As indicated in the prior Office Action, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. Further, a known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use. Applicant argues that there is no assurance that the combination with Ochoa '983 would lead to activated lymphocytes derived from a viral infected patient and then adminstration of the activated lymphocytes to the patient. However, obviousness only requires a reasonable expectation of success not absolute predictability. In this case, as indicated in the prior Office Action, Babbitt et al. and Ochoa '353 both teach and/or suggest activation of autologous T-lymphocytes from virally infected patients. As such, the Applicant's arguments as to Wallace et al. and Ochoa '983 are without merit. This rejection is based on a combination of references. As such, there is no requirement that Wallace disclose adoptive immunotherapy or that Ochoa '983 disclose autologous immunotherapy. One of ordiinary skill in the art is not an automaton. It is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. See KSR v. Teleflex, 550 U.S. ___, Slip Opinion at pages 16, 17. As such, the mere fact that Wallace was directed to establishing a cell line or that the example disclosed in Ochoa '983 was directed to adoptive immunotherapy is insufficient to overcome the rejection. The methods of activating the T-cells, whether, autologous, adoptive or establishing a cell line, involve the same or similar techniques, i.e. using anti-CD3 and/or other antigens, and/or Il-2 to activate the T-cells. One of ordinary skill in the art, having knowledge of immunology and Babbitt et al. and Ochoa et al. '353 would understand that Wallace supports the assertion that activated T-cells from virally infected patients would be effective when reintroduced into said patient. The Applicant's arguments as to Sanamaria are equally without merit. Again, the mere fact that the stated purpose of said reference is to establish a T-cell line is without merit. There is no requirement that Santmaria teach that it is possible to use the method in adoptive immunotherapy. However, Santamaria clearly indicates that the activated T-cells are of importance in the study of cellular immunology. The preferred cultivation time does not exclude longer cultivation times and the ability to grow the T-cells long term does not preclude one from using the activated T-cells after a shorter period of time. The key point is that the combination of solid phase anti-CD3 antibodies and Il-2 allow the activated T-cells to maintain their activity without the presence of CMV antigen or CMV antigen presenting cells (See Pages 7 and 9 of Santamaria). With respect to Sekine, as indicated above, one of ordinary skill in the art is able to use elements in the prior art which are designed to solve different problems. The mere fact that the activated T-cells are used in the treatment of cancer patients does not provide any evidence that the advantage of using immobilized anti-CD3 versus soluble anti-CD3 antibodies in expanding the T-cell number would not be realized when the T-cells are derived from a virally infected patient. In fact, Ochoa '353 and Babbitt et al. disclose that the activation techniques can be used to activate T-cells for the treatment of cancer and for the treatment of viral infections. As such, Sekine is not different from Ochoa '353 in purpose, method or subject for therapy. Contrary to the Applicant's arguments, there is nothing confusing about the teachings of the prior art. The prior art as a whole teaches or suggests the combination of solid phase anti-CD3 and Il-2 to activate autologous T-cells in virally infected patients. Although some of the prior art disclose exposing the T-cells to viral antigens in vitro, none of the prior art specifically states that a viral antigen must be present for anti-CD3 and Il-2 to activate the T-cell and both Ochoa '353 and Babbit et al. disclose or suggest activation techniques that do not require that viral antigens and/or viral antigen presenting cells be introduced in vitro in order to activate the T-cells. Finally, since the purpose of the references does not overcome the rejection, the mere fact that six references were used is not sufficient to overcome the rejection. In any case, as indicated above, the references are not so different that one of ordinary skill in the art would not be able to recognize, use and combine and/or modify the teachings of said references to arrive at the claimed invention..